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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,891	11/17/2000	Susan R. Webb	TSRI 536.1Div2	7205

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EXAMINER	
DECLOUX, AMY M	
ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/715,891	Webb et al.
Examiner	**Art Unit**
D Cloux, Amy	1644

-- The MAILING DATE of this communication appears on th cov r sh t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 21, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *61-84 and 114-148* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *61-84 and 114-148* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Detailed Action

1. A restriction is required under 35 USC 121 between one of the following groups:

I. Claims 61-82, drawn to a method of producing a synthetic antigen presenting cell comprising transforming a cell with a vector capable of expressing an MHC class II α-chain gene, a MHC class II β-chain gene, and at least one accessory molecule,

II. Claim 83, drawn to a method of producing a synthetic antigen presenting cell (APC) comprising providing a cell lacking a gene encoding at least one of MHC class II α-chain, MHC class II β-chain and an accessory molecule, and transforming the cell with an expressible gene for each of said genes lacking in the cell,

III. Claim 84, drawn to a method of producing a synthetic antigen presenting cell (APC) comprising providing a cell lacking a gene encoding at least one of MHC class II α-chain, MHC class II β-chain, an accessory molecule and an antigen processing assisting molecule, and transforming the cell with an expressible gene for each of said genes lacking in the cell,

IV. Claims 114-134, drawn to a method for activating CD4+ T cells in vitro, comprising contacting a synthetic antigen presenting cell (APC) with a peptide library in vitro, contacting the peptide loaded MHC Class II heterodimer with CD4+ T cells, separating the activated CD4+ T cells from the APC, adding the activated CD4+ T cells to an acceptable carrier to form a suspension, and administering the suspension to a patient, wherein said APC comprises a MHC α-chain gene, a MHC β-chain gene, and at least one accessory molecule, classified in class 424, subclass 193.1, and class 436, subclass 536,

V. Claims 135-139, drawn to a method for activating CD4+ T cells in vitro, comprising contacting a cell fragment from the APC of a synthetic antigen presenting cell (APC) with a peptide library in vitro, contacting the peptide loaded MHC Class II heterodimer with CD4+ T cells, separating the activated CD4+ T cells from the APC, adding the activated CD4+ T cells to an acceptable carrier to form a suspension, and administering the suspension to a patient, wherein said APC comprises a MHC α-chain gene, a MHC β-chain gene, and at least one accessory molecule, classified in class 424, subclass 193.1, and class 436, subclass 536,

VI. Claims 140-148, drawn to a method of altering a CD4+ T cell mediated immune response to treat a patient comprising analyzing the patient for patient specific cytokine profile, collecting the CD+ T cells from the patient, contacting the CD4+ T cells with a synthetic APC, wherein said APC comprises a MHC class II α-chain gene, a MHC class II β-chain gene, and at least one accessory molecule, and returning the

activated CD4+ T cells to the patient, classified in class 424, 184.1.

The inventions are distinct, each from the other because:

2. Groups I-VI are drawn to distinct methods because the endpoints of Groups I/II/III, Groups IV/V and Group VI are different. Though the endpoints of Groups I, II and III are the same, they differ in their process steps; Group I comprises a cell not necessarily lacking any genes, group II comprises a cell lacking at least one of three genes, and Group III comprises a cell lacking at least one of four genes. Though the endpoints of Groups IV and V are the same, they differ in their process steps; the former comprises contacting a synthetic antigen presenting cell (APC) with a peptide library, while the latter comprises contacting a cell fragment from the APC of a synthetic antigen presenting cell (APC) with a peptide library. Therefore, Groups I-VI are patentably distinct, each from the other.

3. A) If Group I or II is elected, the applicant is further required under 35 U.S.C. 121:

I) to elect a method of producing a synthetic antigen presenting cell comprising transforming a cell with a vector capable of expressing a **specific MHC class II α-chain gene**,

II) to elect a method of producing a synthetic antigen presenting cell comprising transforming a cell with a vector capable of expressing a **specific MHC class II β-chain gene**,

III) to elect a method of producing a synthetic antigen presenting cell comprising transforming a cell with a vector capable of expressing a **specific accessory molecule gene**, or a **specific combination** of **specific accessory molecule genes**, such as a costimulatory molecule as recited in claim 71, or an adhesion molecule as recited in claim 73, or a survival molecule as recited in claim 75,

a) if a costimulatory molecule is elected, then applicant is further required to elect a **specific costimulatory molecule** such as B7.1 as recited in claim 72,

b) if an adhesion molecule is elected, then applicant is required to elect a **specific adhesion molecule** such as ICAM-1 as recited in claim 74,

c) if a survival molecule is elected, then applicant is further required to elect a **specific survival molecule** such as CD70 as recited in claim 76,

IV) to elect a method of producing a synthetic antigen presenting cell comprising transforming a **specific cell**, such as an insect cell as recited in claim 68

a) if an insect cell is elected, applicant is further required to elect a specific insect cell such as drosophila as recited in claim 117,

B) If Group III is elected, the applicant is further required under 35 U.S.C. 121:

I) to elect a method of producing a synthetic antigen presenting cell comprising transforming a cell with a vector capable of expressing a **specific MHC class II α-chain gene**,

II) to elect a method of producing a synthetic antigen presenting cell comprising transforming a cell with a vector capable of expressing a **specific MHC class II β-chain gene**,

III) to elect a method of producing a synthetic antigen presenting cell comprising transforming a cell with a vector capable of expressing a **specific accessory molecule gene**, or a **specific combination** of **specific accessory molecule genes**, such as a costimulatory molecule as recited in claim 71, or an adhesion molecule as recited in claim 73, or a survival molecule as recited in claim 75, or a **specific** antigen processing assisting molecule as recited in claim 84,

a) if a costimulatory molecule is elected, then applicant is further required to elect a **specific costimulatory molecule** such as B7.1 as recited in claim 72,

b) if an adhesion molecule is elected, then applicant is required to elect a **specific adhesion molecule** such as ICAM-1 as recited in claim 74,

c) if a survival molecule is elected, then applicant is further required to elect a **specific survival molecule** such as CD70 as recited in claim 76,

IV) to elect a method of producing a synthetic antigen presenting cell comprising transforming a **specific cell**, such as an insect cell as recited in claim 68

a) if an insect cell is elected, applicant is further required to elect a specific insect cell such as drosophila as recited in claim 117,

C) If Group IV or V is elected, the applicant is further required under 35 U.S.C. 121:

I) to elect a method for activating CD4+ T cells in vitro, comprising contacting a synthetic antigen presenting cell (APC) with a peptide library in vitro wherein said synthetic antigen presenting cell comprises a **specific MHC class II α-chain gene**,

II) to elect a method for activating CD4+ T cells in vitro, comprising contacting a synthetic antigen presenting cell (APC) with a peptide library in vitro wherein said synthetic antigen presenting cell comprises a **specific MHC class II β-chain gene**,

III) to elect a method for activating CD4+ T cells in vitro, comprising contacting a synthetic antigen presenting cell (APC) with a peptide library in vitro wherein said synthetic antigen presenting cell comprises a **specific accessory molecule gene**, or a **specific combination** of **specific accessory molecule genes**, such as a costimulatory molecule as recited in claim 123, or an adhesion molecule as recited in claim 125, or a survival molecule as recited in claim 127,

a) if a costimulatory molecule is elected, then applicant is further

required to elect a **specific costimulatory molecule** such as B7.1 as recited in claim 124,

b) if an adhesion molecule is elected, then applicant is required to elect a **specific adhesion molecule** such as ICAM-1 as recited in claim 126,

c) if a survival molecule is elected, then applicant is further required to elect a **specific survival molecule** such as CD70 as recited in claim 128,

IV) to elect a method for activating CD4+ T cells in vitro, comprising contacting a synthetic antigen presenting cell (APC) with a peptide library in vitro wherein said cell is a **specific cell**, such as an insect cell as recited in claim 121,

a) if an insect cell is elected, applicant is further required to elect a **specific insect cell** such as drosophila as recited in claim 122,

V) to elect a method for activating CD4+ T cells in vitro, comprising contacting a synthetic antigen presenting cell (APC) with a peptide library in vitro wherein said peptide library is a **specific peptide library,**

D) If Group VI is elected, then applicant is required to elect

I) a method of altering a CD4+ T cell mediated immune response to treat a patient comprising contacting the CD4+ T cells with a synthetic APC, wherein said APC comprises **a specific MHC class II α-chain gene,**

II) a method of altering a CD4+ T cell mediated immune response to treat a patient comprising contacting the CD4+ T cells with a synthetic APC, wherein said APC comprises **a specific MHC class II β-chain gene,**

III) a method of altering a CD4+ T cell mediated immune response to treat a patient comprising contacting the CD4+ T cells with a synthetic APC, wherein said APC comprises a **specific accessory molecule gene**, or a **specific combination** of **specific accessory molecule gene**s, such as a costimulatory molecule as recited in claim 123, or an adhesion molecule as recited in claim 125, or a survival molecule as recited in claim 127,

a) if a costimulatory molecule is elected, then applicant is further required to elect a **specific costimulatory molecule** such as B7.1 as recited in claim 124,

b) if an adhesion molecule is elected, then applicant is required to elect a **specific adhesion molecule** such as ICAM-1 as recited in claim 126,

c) if a survival molecule is elected, then applicant is further required to elect a **specific survival molecule** such as CD70 as recited in claim 128,

IV) to elect a method of altering a CD4+ T cell mediated immune response to treat a patient comprising contacting the CD4+ T cells with a synthetic APC, wherein said APC is a **specific cell**, such as an insect cell as recited in claim 121,

a) if an insect cell is elected, applicant is further required to elect a **specific insect cell** such as drosophila as recited in claim 122,

V) to elect a method of altering a CD4+ T cell mediated immune

response to treat a patient comprising contacting the CD4+ T cells with a synthetic APC, wherein said APC has been pulsed with a **specific peptide or peptide library**,

VI) to elect a method of altering a CD4+ T cell mediated immune response to treat a condition in a patient comprising contacting the CD4+ T cells with a synthetic APC, wherein said condition is a **specific condition** such as an autoimmune disease as recited in claim 141, or an allergy as recited in claim 145.

a) if an autoimmune disease is elected, then applicant is required to elect a **specific autoimmune disease** such as diabetes as recited in claim 142,

B) if an allergic condition is elected, applicant is required to elect a **specific allergy**, such as asthma as recited in claim 146

VII) to elect a method of altering a CD4+ T cell mediated immune response to treat a condition in a patient comprising analyzing the patient for patient specific cytokine profile, wherein said profile is produced by a **specific T cell response**, such as a CD4+ Th1 type response as recited in claim 143, or a CD4+ Th2 type response as recited in claim 147.

a) if a CD4+ Th1 type response is elected, then applicant is required to elect a **specific combination of cytokines** such as one or more of the cytokines recited in claim 144,

b) if a CD4+ Th2 type response is elected, then applicant is required to elect a **specific combination of cytokines** such as one or more of the cytokines recited in claim 148,

4. Claims 61-84 and 114-148 are generic, in at least one aspect.

5. The species are distinct each from the other for the following reasons:

A) Specific MHC Class II chains, each encompass physical structures with unique properties.

B) Specific accessory molecules differ with respect to their biophysical structure and function.

C) Specific peptides differ with respect to their amino acid sequences and their biophysical structure and function.

D) Peptide libraries differ with respect to the amino acid sequences and/or length of the encompassed peptides

E) Specific cells differ with respect to their structure, composition and function,

F) Specific cytokines differ with respect to their structure and function,

G) specific conditions differ with respect to their etiologies and symptoms,

H) Specific CD4+ T cell responses differ with respect to the cells and cytokines involved,

6. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims

are generic is considered non-responsive unless accompanied by an election.

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. a dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. a Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to

responses to Written Restrictions.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers **(other than elections)** should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
March 25, 2002
Amy DeCloux
3-25-02